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(54) Title: FORMULATIONS COMPRISING IMIQUIMOD OR OTHER IMMUNE RESPONSE MODIFIERS FOR TREATING MUCOSAL CONDITIONS

(57) Abstract: Immune response modifier (IRM) compounds - imidazoquinoline amines, imidazopyridine amines, 6,7-fused cycloalkylimidazopyridine amines, 1,2-bridged imidazoquinoline amines, thiazolo- and oxazolo- quinolinamines and pyridinamines, imidazonaphthyridine and tetrahydroimidazonaphthyridine amines - are useful for the treatment of conditions at and below the mucosal surfaces by administering a therapeutically effective amount of such compounds to the mucosal surface. Novel pharmaceutical formulations are provided. In one embodiment, the pharmaceutical formulations are advantageous for treatment of cervical conditions such as cervical dysplasias including cervical intraepithelial neoplasias.

INTERNATIONAL SEARCH REPORT

Intern Application No

PCT/US 00/00370

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE PHIN 'Online! "3M Pharmaceuticals unveils research and development and expansion plans" retrieved from STM INTERNATIONAL Database accession no. 96:11586 XP002148627 page 2 & SCRIP, no. 2138, 1996, pages 10-..., ---	1-7, 14
X	DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1991 HARRISON C J ET AL: "EFFECTS OF CYTOKINES AND R-837 A CYTOKINE INDUCER ON UV-IRRADIATION AUGMENTED RECURRENT GENITAL HERPES IN GUINEA-PIGS" Database accession no. PREV199192050148 XP002148628 abstract & ANTIVIRAL RESEARCH, vol. 15, no. 4, 1991, pages 315-322, ISSN: 0166-3542 ---	1-4
X	DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1988 HARRISON C J ET AL: "MODIFICATION OF IMMUNOLOGICAL RESPONSES AND CLINICAL DISEASE DURING TOPICAL R-837 TREATMENT OF GENITAL HSV-2 INFECTION" Database accession no. PREV198987085969 XP002148629 abstract & ANTIVIRAL RESEARCH, vol. 10, no. 4-5, 1988, pages 209-224, ISSN: 0166-3542 ---	1-4
X, Y	MILLER R L ET AL: "REVIEW ARTICLE. IMIQUIMOD APPLIED TOPICALLY: A NOVEL IMMUNE RESPONSE MODIFIER AND NEW CLASS OF DRUG" INTERNATIONAL JOURNAL OF IMMUNOPHARMACOLOGY, ELMSFORD, NY, US, vol. 21, January 1999 (1999-01), pages 1-14, XP000900725 ISSN: 0192-0561 page 2, last line -page 3, line 1-4; table 1 ---	1-22 -/-

INTERNATIONAL SEARCH REPORT

Internat'l Application No

PCT/US 00/00370

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, Y	<p>CHOLLET J L ET AL: "DEVELOPMENT OF A TOPICALLY ACTIVE IMIQUIMOD FORMULATION" PHARMACEUTICAL DEVELOPMENT AND TECHNOLOGY, NEW YORK, NY, US, vol. 4, no. 1, January 1999 (1999-01), pages 35-43, XP000900717 ISSN: 1083-7450 abstract page 41, left-hand column</p> <p>---</p>	1-22
Y	<p>DITTGEN M ET AL: "ACRYLIC POLYMERS. A REVIEW OF PHARMACEUTICAL APPLICATIONS" STP PHARMA PRATIQUES, PARIS, FR, vol. 7, no. 6, 1997, pages 403-437, XP000900605 ISSN: 1157-1497 page 421, left-hand column, paragraph 4</p> <p>-----</p>	1-22

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

The expression "immune response modifier" and the generic chemical groups mentioned in the independent claims 1, 6, 14, 15 and 21 encompass an extremely large number of compounds. Furthermore, the only compound supported by the description is imiquimod (first mentioned in claim 2). In view of this lack of clarity (Art. 6 PCT) and support (Art. 5 PCT) a complete search was not possible. The search had to be limited to the two specific compounds mentioned in the claims.

Although the subject-matter of claims 15-22 constitutes a separate invention, directed to a specific pharmaceutical composition, an objection of lack of unity is not raised, in view of the fact that this matter could be searched without a major additional effort.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 00/00370

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ^a	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 24436 A (MINNESOTA MINING & MFG) 11 June 1998 (1998-06-11) abstract page 5, line 22-30; claims 20-23 ---	1,3-6,8, 14
X	WO 97 41884 A (PHARMA PACIFIC PTY LTD) 13 November 1997 (1997-11-13) page 8, line 22 -page 9, line 2; claims 1,22,34 --- -/-	1,2

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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